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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,789	07/31/2001	Gary Lynch	1819.0030002/MAC	1493

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EXAMINER
ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/917,789	LYNCH ET AL.	
	Examin r	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-88* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachm nt(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to methods of determining the effect of a substance on neuronal damage induced by disruptors of lysosomal activity or inducers of cathepsin D, classified in class 435, subclass 4.

II. Claims 13-26, drawn to methods of determining the effect of a substance on neuronal damage induced by a decrease in cholesterol , classified in class 435, subclass 4.

III. Claims 27-39, drawn to methods of determining the effect of a substance on the inhibition by a protease inhibitor of neuronal damage that was induced by disruptors of lysosomal activity or inducers of cathepsin D, classified in class 435, subclass 4.

IV. Claims 40-53, drawn to methods of determining the effect of a substance on the inhibition by a protease inhibitor of neuronal damage that was induced by a decrease in cholesterol, classified in class 435, subclass 4.

V. Claims 54-59 and 89-94, drawn to methods of inhibiting tau proteolysis with a protease inhibitor, classified in class 514, subclass 1.

VI. Claims 60-71, drawn to methods of determining the effect of a substance on the inhibition by a kinase inhibitor of neuronal damage that was induced by disruptors

of lysosomal activity or inducers of cathepsin D, classified in class 435, subclass 4.

VII. Claims 72-88, drawn to methods of determining the effect of a substance on the inhibition by a kinase inhibitor of neuronal damage that was induced by a decrease in cholesterol, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The methods of Invention I are distinct from those of Invention II because they require different reagents and identify a non-coextensive set of modulators.

The methods of Invention I are not related to those of Invention III because they identify different modulators and have different outcome measures.

The methods of Invention I are not related to those of Invention IV because they require different reagents, identify different modulators, and have different outcome measures.

The methods of Invention I are not related to those of Invention V. They require different reagents and have different goals and distinct outcome measures.

The methods of Invention I are not related to those of Invention VI because they identify different modulators and have different outcome measures.

The methods of Invention I are not related to those of Invention VII because they require different reagents, identify different modulators, and have different outcome measures.

The methods of Invention II are not related to those of Invention III because they require different reagents, identify different modulators, and have different outcome measures.

The methods of Invention II are not related to those of Invention IV because they identify different modulators and have different outcome measures.

The methods of Invention II are not related to those of Invention V. They require different reagents and have different goals and distinct outcome measures.

The methods of Invention II are not related to those of Invention VI because they require different reagents, identify different modulators, and have different outcome measures.

The methods of Invention II are not related to those of Invention VII because they identify different modulators and have different outcome measures.

The methods of Invention III are distinct from those of Invention IV because they require different reagents and identify a non-coextensive set of modulators.

The methods of Invention III are not related to those of Invention V. They require different reagents and have different goals and distinct outcome measures.

The methods of Invention III are distinct from those of Invention VI because they require different reagents and identify a non-coextensive set of modulators.

The methods of Invention III are distinct from those of Invention VII because they require different reagents and identify a non-coextensive set of modulators.

The methods of Invention IV are not related to those of Invention V. They require different reagents and have different goals and distinct outcome measures.

The methods of Invention IV are distinct from those of Invention VI because they require different reagents and identify a non-coextensive set of modulators.

The methods of Invention IV are distinct from those of Invention VII because they require different reagents and identify a non-coextensive set of modulators.

The methods of Invention V are not related to those of Invention VI. They require different reagents and have different goals and distinct outcome measures.

The methods of Invention V are not related to those of Invention VII. They required different reagents and have different goals and distinct outcome measures.

The methods of Invention VI are distinct from those of Invention VII because they require different reagents and identify a non-coextensive set of modulators.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the searches required for the different groups are not coextensive, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

FOR GROUPS I, II, III, IV, VI, and VII, THERE ARE TWO GROUPS OF SPECIES:

1. method of detection:

    a. Neurofibrillary tangles

    b. Tau phosphorylation

    c. Tau proteolysis

    d. Cytokine production

e. Microglia reaction

f. Brain inflammatory reaction

g. Conversion of p25 to p35.

h. Cdk 5 activity

i. MAPK activity

These are distinct methods of detection that would detect non-coextensive agents and outcomes. Results with one would not render results with another obvious or predictable. If any of these groups is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 5-12 are generic for Invention I, claims 13 and 17-26 are generic for Invention II, claims 27 and 31-39 are generic for Invention III, claims 40 and 44-53 are generic for Invention IV, claims 60 and 64-71 are generic for Invention VI, and claims 72 and 76-88 are generic for Invention VII

2. Apolipoprotein E

a. Apolipoprotein E-deficient cells

b. Cells containing Apolipoprotein E4

These cells have different biochemical properties and would not be expected to react to agents in the same way. Results with one cell type would not render results with another obvious or predictable. If any of these groups is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-10 are generic for Invention I, claims 13-23 and 26 are generic for Invention II, claims 27 -36 and 38 are

generic for Invention III, claims 40-50 and 53 are generic for Invention IV, claims 60-69 are generic for Invention VI, and claims 72-82 and 85-89 are generic for Invention VII.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
September 6, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER